

COMMONWEALTH of VIRGINIA

Department of Health

M. NORMAN OLIVER, MD. MA STATE HEALTH COMMISSIONER

PO BOX 2448 RICHMOND, VA 23218

November 15, 2019

TTY 7-1-1 OR 1-800-828-1120

Matthew Jenkins, Esquire Hunton Andrews Kurth Riverfront Plaza, East Tower 951 East Byrd Street Richmond, Virginia 23219-4074

Thomas J. Stallings, Esquire **McGuireWoods** 800 East Canal Street Richmond, Virginia 23219

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RE: CERTIFICATE OF PUBLIC NEED

(COPN or "Certificate")

No. VA-04683

(REOUEST No. VA-8446)

Bon Secours - St. Mary's Hospital of Richmond, Inc.

("Bon Secours")

Henrico County, Planning District (PD) 15 Expand CT Services through Addition of a Dedicated Intraoperative CT Unit (the "St. Mary's project")

COPN Request No. VA-8456 HCA Health Services of Virginia, Inc. (HCA) Henrico County, PD 15 Establish a Specialized Center for CT Services (the "Henrico Doctors project")

Dear Mr. Jenkins and Mr. Stallings:

In accordance with Article 1.1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 et seq.) of the Code of Virginia, I have reviewed the applications captioned above and the record compiled in relation to the projects proposed in those applications. As required by Subsection B of Virginia Code § 32.1-102.3, I have considered all matters, listed therein, that must be taken into account in making a determination of public need.



Matthew Jenkins, Esq. Thomas J. Stallings, Esq. November 2019 Page 2 of 3

I have received, reviewed and adopted the enclosed findings, conclusions and recommended decision of the adjudication officer who convened the informal fact-finding conference to discuss the applications, and who reviewed the administrative record pertaining to the proposed projects.

Based on my review of the projects and on the recommended decision of the adjudication officer, I am approving the project proposed by Bon Secours (the "St. Mary's Project") and denying the project proposed by HCA (the "Henrico Doctors project"). The first project merits approval and should result in issuance of a Certificate. It is necessary to meet a public need. The second project does not merit approval and is not necessary to meet a public need.

The reasons for my decision include the following:

- (i) The St. Mary's project is consistent with the State Medical Facilities Plan, or is in overall harmony or general agreement with the SMFP and public interests and to which that plan is dedicated;
- (ii) Capital costs associated with the St. Mary's project are reasonable and it is financially feasible;
- (iii) There is no known opposition to the St. Mary's project;
- (iv) HCA has not demonstrated a public need for the Henrico Doctors project;
- (v) The Henrico Doctors project is not consistent with the SMFP;
- (vi) The geographical area proposed for the Henrico Doctors project location is already well served by existing providers of CT services and emergency department services without the duplication that the Henrico Doctors project would bring;
- (vii) If approved, the Henrico Doctors project is likely to have a negative impact on existing providers of CT and emergency department services in the western portion of PD 15, which is already well served by several existing providers of CT and emergency department services.

In accordance with Rule 2A:2 of the Rules of the Supreme Court of Virginia, any aggrieved party to an administrative proceeding choosing to appeal a case decision shall file, within 30 days after service of the case decision, a signed notice of appeal with "the agency secretary." I would consider such a notice sufficiently filed if it were addressed and sent to the Office of the State Health Commissioner, and timely received by that office, at the James Madison Building, Thirteenth Floor, 109 Governor Street, Richmond, Virginia 23219. Under

^{*} In accordance with Va. Code § 2.2-4023, the signed original of these final agency case decisions "shall remain in the custody" of the Department, while the applicants are receiving a photocopy of the original case decision letter.

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the Rule, when service of a decision is "accomplished by mail," three days are added to the 30-day period.

Sincerely,

M. Norman Oliver, MD, MA State Health Commissioner

cc: Danny Avula, MD, MPH

Director, Henrico Health District

Vanessa MacLeod, Esq.

Assistant Attorney General

Deborah Waite

Virginia Health Information

Erik O. Bodin, III

Director, Division of

Certificate of Public Need

Douglas R. Harris, JD

Adjudication Officer

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COMMONWEALTH OF VIRGINIA

DEPARTMENT OF HEALTH

THIS CERTIFIES THAT Bon Secours - St. Mary's Hospital of Richmond, Inc. is authorized to initiate the proposal as described below.

NAME OF FACILITY: Bon Secours St. Mary's Hospital

LOCATION: 5801 Bremo Road, Richmond, Virginia 23226

OWNERSHIP AND CONTROL: Bon Secours - St. Mary's Hospital of Richmond, Inc.

Mary's Hospital. The authorized Capital costs associated with this project total \$2,300,000. The project is expected to be SCOPE OF PROJECT: Expand CT services through the addition of a dedicated intraoperative CT unit at Bon Secours - St. completed by February 1, 2020. This certificate is issued with the condition that appears on its reverse.



to fulfill these conditions. This Certificate is non-transferable and is limited to the location, ownership, control and scope of the project shown shall be submitted to the State Health Commissioner within twelve (12) months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Commissioner reserves the right not to renew this Certificate in the event the applicant fails Pursuant to Chapter 4, Article 1:1 of Title 321, Sections 321-1021 through 321-10212 of the Code of Virginia (1950), as amended and the policies and procedures promulyated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial and continuing progress towards implementation of the proposal within twelve (12) months from the date of issuance. A progress report

Certificate Number: VA-04683

November 15, 2019 Date of Issuance:

November 15, 2020 Expiration Date:

M Norman Oliver, MD, MA, State Health Commissioner

condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Security Act, 42 U.S.C. § 1395 et seq. Compliance with this condition will be documented to the Division of Certificate of with the preceding requirement. Bon Secours - St. Mary's Hospital of Richmond, Inc. will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided to individuals pursuant to this amount equal to at least 3.4% of Bon Secours - St. Mary's Hospital of Richmond, Inc.'s total patient services revenue derived from intraoperative CT services provided at Bon Secours - St. Mary's Hospital as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance service, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate Bon Secours - St. Mary's Hospital of Richmond, Inc. will provide intraoperative CT services to all persons in need of this Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. RECOMMENDATION TO THE
STATE HEALTH COMMISSIONER
FOLLOWING AN INFORMAL FACT FINDING CONFERENCE
REGARDING CERTIFICATE OF PUBLIC NEED
(COPN, or "Certificate") REQUEST NUMBERS:

COPN Request No. VA-8446
Bon Secours - St. Mary's Hospital of Richmond, Inc.
Planning District 15
Expand CT Services through Addition of
a Dedicated Intraoperative CT Unit
(the "St. Mary's project");

COPN Request No. VA-8456
HCA Health Services of Virginia, Inc.
d/b/a Henrico Doctors Hospital
Planning District 15
Establish a Specialized Center for CT Services
(the "Henrico Doctors project")

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I. Introduction

The present document contains two recommended case decisions, one each on the above-captioned applications for a COPN. It is submitted to the State Health Commissioner (hereinafter, the "Commissioner") for his adoption.

These recommended decisions, made in response to competing applications, or proposed projects, follow an informal fact-finding conference (IFFC) conducted in accordance with the Virginia Administrative Process Act (the APA, Virginia Code § 2.2-4000 et seq.)¹ and Virginia Code § 32.1-102.6. It reflects a review of the Virginia Department of Health's ("Department's") administrative record of the cases placed into the record by the applicants seeking approval of the proposed projects captioned above. The present document discusses the most salient facts and arguments made in gauging the projects against the statutory considerations in the COPN law.

II. Authority

Article 1 of Chapter 4 of Title 32.1 (§ 32.1 – 102.1 et seq.) of the Virginia Code (the "COPN law") addresses medical care facilities and provides that "[n]o person shall commence any project without first obtaining a [COPN] issued by the Commissioner." The COPN law provides a definition of "project," under which each of the above-captioned proposals fall.² The law requires their review to determine whether a public need exists for any of them.

Specifically, Va. Code § 2.2-4019.

² Va. Code § 32.1-102.1, definition of "[p]roject."

III. Procedural Background; Incorporation of the DCOPN Staff Report

An IFFC on the projects was held on July 30, 2019, in Henrico County. Principal agents of the applicants appeared and were represented by legal counsel. The applicants were given the opportunity to present detailed evidence on the merits of their respective projects through the submission of written exhibits and the transcribing of witnesses' testimony.

A facilities planning analyst from the Department's Division of Certificate of Public Need (DCOPN),³ attended the IFFC and presented that division's analysis and recommendation dated July 19, 2019 (the "DCOPN staff report"). DCOPN recommends conditional approval of the St. Mary's project and denial of the Henrico Doctors project. At the IFFC, a briefing schedule was devised for post-IFFC submittals. The close of the administrative record on the projects occurred on September 19, 2019.

By reference, I incorporate the DCOPN staff report into the present document for the purpose of establishing or corroborating basic and unrebutted facts and demonstrating analysis that supports or helps substantiate the evidentiary bases on which the recommendations made herein rest.

III. Findings of Fact and Conclusions of Law

I have reviewed the administrative record relating to the applications. Based on the administrative proceedings and record, I make the following findings of fact and conclusions of law.

- 1. Bon Secours St. Francis Hospital of Richmond, Inc. ("St. Mary's") is a not-for-profit, non-stock Virginia corporation. Bon Secours proposes to add one intraoperative CT scanner to be housed in existing storage space within the surgical suite. The applicant has provided an assurance that the new CT scanner would not be used for diagnostic purposes. Total capital costs for the project are \$2,300,000. These costs would be covered by accumulated reserves.
- 2. HCA Health Services of Virginia, Inc. (HCA) is a for-profit, Virginia Stock corporation. HCA proposes to develop a freestanding imaging center with one CT scanner in conjunction with a freestanding emergency department in western Henrico County. Total capital costs for the project are \$12,120,000. These costs would be covered by accumulated reserves.
- 3. A. The Proposed Projects in Relation to Specific Provisions of the Eight Statutory

 Considerations. Facts and conclusions⁴ regarding the two projects and relating directly to the eight considerations of public need,⁵ set forth and enumerated in subsection B of Virginia Code § 32.1-

³ DCOPN is the work unit, or "division," within the Department that is composed of the Commonwealth's professional health facilities planning staff.

⁴ Some statements and conclusions, appearing below and placed in direct relation to one statutory consideration, may carry significance and relevance in addressing one or more other statutory considerations.

As set forth in bold below, the statutory considerations are set apart for discussion. They are as set forth in statute verbatim, except that the first word of some discrete items have been capitalized, punctuation at the end of discrete

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102.3,6 as amended (the "statutory considerations"), divided and appearing in bold type below, are set forth in relation to each statutory consideration. General reference is made to the DCOPN staff report for additional and corroborative findings of fact consistent with conclusions of law drawn below.

Salient facts and conclusions about the projects and relating to each statutory consideration include:

1. The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

There are 48 CT scanners currently serving PD 15. There are no apparent geographic, cultural or transportation barriers to access to care. The St. Mary's project would improve access to care. Intraoperative CT services are not available at any facility within the Bon Secours Richmond Health System. Intraoperative CT allows surgery to proceed with real time imaging benefits within an operating room setting, such as improved tissue visualization and the ability to see the location of surgical instruments in relation to the patient. The CT scanner would not be used for diagnostic purposes.

The Henrico Doctors project would not improve access to care. CT and emergency department services already are widely available from multiple providers in western Henrico County. No fewer than 12 CT locations and five emergency departments are located within ten driving miles of the proposed site. This area has been described as "saturated" with CT resources. PD 15's CT services are concentrated in western PD 15. There is no public need for an additional CT service in the western portion of PD 15.

- 2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following:
- (i) The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served;

DCOPN received numerous letters supporting the St. Mary's project from Bon Secours employees, and from Tuckahoe Orthopaedics. DCOPN received six letters of support for the Henrico Doctors project, including one from the county manager for Henrico County. Twenty-five persons attended the public hearing. Twelve of those indicated support for the St. Mary's project and none indicated opposition. Four persons indicated support for the Henrico Doctors project and 11 indicated opposition. Bon Secours opposes the Henrico Doctors project.

items has been changed in a few instances for parallel relationship, and two dangling usages of "and" have been removed.

⁶ As amended, effective March 25, 2009. See also, Acts of Assembly, 2009, Chapter 175 (House Bill 1598).

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(ii) The availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner;

Given the unique capabilities of the St. Mary's project, no alternative is more reasonable or advantageous than the St. Mary's project. Bon Secours states that

[n]otably, HCA historically has vigorously opposed the addition of diagnostic imaging resources in the very area where HCA now proposes to place a CT scanner, asserting in the review of [projects reviewed in 2015], "maintaining the status quo is a reasonable, and, in fact, necessary alternative to the proposed CT services..."

The status quo is a reasonable alternative to the Henrico Doctors project.

(iii) Any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;

No regional health planning agency serves HPR IV by submitting recommendations to the Commissioner addressing proposed projects within HPR IV.

(iv) Any costs and benefits of the project;

The total costs of the St. Mary's project are \$2,300,000, to be paid out of accumulated reserves. The benefits of placing an intraoperative CT scanner at St. Mary's would include real-time imaging within an operating room setting, improved tissue visualization and the ability to see the location of surgical instruments in relation to the patient. Minimally-invasive surgery would be promoted and the high quality of imaging would support high-risk surgeries.

The total costs of the Henrico Doctors project are \$12,120,000, to be paid through the internal resources of HCA. These costs are considerable, but when taking into account the cost associated with only the purchase of the CT scanner, are consistent with previously approved projects. Locating CT imaging at a freestanding emergency department would allow improvement of diagnoses and treatment in an emergency setting. Better access and shorter transport times for certain residents would result.

Costs represented by capital outlay are not the only costs a project may bring. The Henrico Doctors project would bring the costs associated with locating a CT scanner in an area that is saturated with CT services.

⁹ Bon Secours Proposed Findings and Conclusions at 11.

(v) The financial accessibility of the project to the residents of the area to be served, including indigent residents; and

Each applicant provides assurances that the envisioned services would be available to all patients, regardless of their ability to pay or payment source. Charity care conditions should be attached to any Certificates that issue from this review.

(vi) At the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project.

HCA argues that DCOPN fundamentally misunderstood and misanalysed its application. HCA states that its project should have been analyzed under the SMFP's provision for expansion of a service, 12 VAC 5-230-110. DCOPN instead characterized the Henrico Doctors project as a proposed new site. I do not believe the supposed error is of consequence.

No additional factors relating to the review of these projects are clearly remarkable or appear to call for the exercise of the Commissioner's discretion in identifying or evaluating them in relation to the proposed projects.

3. The extent to which the application is consistent with the State Medical Facilities Plan.

The COPN law requires that "[a]ny decision to issue . . . a [C]ertificate shall be consistent with the most recent applicable provisions of the ["SMFP"] "8 The SMFP, adopted as an amended regulation by the State Board of Health in 2009, and contained in the Virginia Administrative Code (VAC), includes several provisions applicable to a project proposing the establishment or expansion of CT services.

Driving Time. The SMFP's driving time standard, 12 VAC 5-230-90, provides that

CT services should be available within 30 minutes driving time . . . of 95% of the population of a [PD]. . . .

Existing circumstances, according to DCOPN, appear to allow compliance with this normative standard.

Expansion of an Existing Service. The SMFP's expansion standard, 12 VAC 5-230-110, applies to both projects. It provides that

Proposals to expand an existing medical care facility's CT service through the addition of a CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The [C]ommissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the [PD].

⁸ Va. Code § 32.1-102.3.

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St. Mary's three CT scanners, which are utilized at a level that equates to 163.1 percent of the SMFP standard. Further, the scanner that would be added through the St. Mary's project would be for intraoperative use, not for diagnostic use. The St. Mary's project is consistent with this standard.

The Henrico Doctors project does not comply with this standard because it would place a CT in an area saturated with CT services, causing a negative impact on CT services in proximity to the proposed site. HCA contests this, saying the CT would be used primarily for emergency department patients. Regardless, it still would be available for general diagnostic use and would cause a negative impact on existing providers.

<u>Staffing.</u> The SMFP calls for CT services being under the direction of one or more qualified physicians. The applicants have provided assurances that their respective projects would be consistent with this requirement.

4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served.

The St. Mary's project stands to foster beneficial competition. It would improve access to essential health care services due to the existence of intraoperative CT services at only one or two hospitals in PD 15.

The Henrico Doctors project would have a detrimental effect on existing providers of CT and emergency department services in the western portion of PD 15. At least 12 existing CT services are within ten miles of the proposed site; six of these are located within five miles of the proposed site. It would not foster beneficial competition.

5. The relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities.

The St. Mary's project would have an appropriate relationship to the health care system. It would be used exclusively in an operating room setting – not for diagnostic service, bringing the benefits discussed above.

There is a surplus of seven CT scanners in PD 15, according to DCOPN. The Henrico Doctors project would not have an appropriate relationship to the system, as it would place a CT scanner in an area that is saturated with CT services. Such duplication would have a detrimental effect on existing CT services.

6. The feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital.

The St. Mary's project is feasible and would become a useful adjunct to surgical services at St. Mary's.

The Henrico Doctors project has a considerable overall cost and may not be feasible due to the saturation of CT services and emergency department services in the area.

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7. The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) The introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) The potential for provision of services on an outpatient basis; (iii) Any cooperative efforts to meet regional health care needs; and (iv) At the discretion of the Commissioner, any other factors as may be appropriate.

The St. Mary's project would introduce technology used in a novel manner, thereby bringing the benefits discussed elsewhere.

The Henrico Doctors project would not introduce new technology.

No additional factors relating to the review of this project are clearly remarkable or appear to call for the exercise of the Commissioner's discretion in identifying or evaluating them in relation to the proposed projects as gauged under this item under the seventh statutory consideration.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be serve (i) the unique research, training, and clinical mission of the teaching hospital or medical school, and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

Not applicable, without prejudice to the projects.

B. The Proposed Project in Relation to the Eight Statutory Considerations and the COPN Law Generally. In relation to all eight statutory considerations, appearing in bold type above, and upon review of the administrative record compiled in relation to the proposed projects (including the applications, the transcript of the IFFC, the DCOPN staff report and the IFFC-related submittals of the applicants' counsel), I believe that sufficient data and information exist to substantiate the recommendations made below, and that the administrative record presents, overall, a sufficient or compelling basis for approving the St. Mary's project, but not the Henrico Doctors project.

I have explored all issues pertinent to a public need determination in relation to these projects, giving evaluative attention to the salient facts, considerations and argument in the process of adjudicatory review. I present this document and the following recommendations to the Commissioner, for his consideration in making public need determinations on the proposed projects, as called for by law.

IV. Recommendation

Based on my assessment, I conclude that the St. Mary's project merits approval, and that the Henrico Doctors project does not. Bon Secours should receive a Certificate, conditioned to ensure the provision of charity care.

In addition to conclusions drawn throughout this document, specific reasons for my recommendations include:

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- (i) The St. Mary's project is consistent with the SMFP, or is in overall harmony or general agreement with the SMFP and public interests and to which that plan is dedicated;
- (ii) Capital costs associated with the St. Mary's project are reasonable and it is financially feasible;
- (iii) There is no known opposition to the St. Mary's project;
- (iv) HCA has not demonstrated a public need for the Henrico Doctors project;
- (v) The Henrico Doctors project is not consistent with the SMFP;
- (vi) The geographical area proposed for the Henrico Doctors project location is already well served by existing providers of CT services and emergency department services without the duplication that the Henrico Doctors project would bring;
- (vii) If approved, the Henrico Doctors project is likely to have a negative impact on existing providers of CT and emergency department services in the western portion of PD 15, which is already well served by several existing providers of CT and emergency department services.

Respectfully submitted,

November 1, 2019

Douglas R. Harris, JD Adjudication Officer

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